



Monitoring of medicinal products authorized based on a single-arm trial: The case of a CAR-T cell therapy

Callreus, Torbjorn; Sessa, Maurizio; El-Galaly, Tarec; Jerkeman, Mats; Andersen, Morten

DOI:
[10.1002/pds.4732](https://doi.org/10.1002/pds.4732)

Publication date:
2019

Document version
Publisher's PDF, also known as Version of record

Document license:
[CC BY](#)

Citation for published version (APA):
Callreus, T., Sessa, M., El-Galaly, T., Jerkeman, M., & Andersen, M. (2019). *Monitoring of medicinal products authorized based on a single-arm trial: The case of a CAR-T cell therapy*. 190-190.
<https://doi.org/10.1002/pds.4732>

Abstracts

The burden of medication errors and preventable adverse drug events in critically ill children: A systematic review

*A.A. Alghamdi¹, R.N. Keers^{1,3}, A. Sutherland^{1,4}, D.M. Ashcroft^{1,2}

¹Centre for Pharmacoepidemiology and Drug Safety, Division of Pharmacy and Optometry, School of Health Sciences, Manchester Academic Health Science Centre, University of Manchester, Manchester, UK, ²NiHR Greater Manchester Patient Safety Translational Research Centre, Manchester Academic Health Science Centre, University of Manchester, Manchester, UK, ³Pharmacy Department, Greater Manchester Mental Health NHS Foundation Trust, Crumpsall, Manchester, UK, ⁴Pharmacy Department, Royal Manchester Children's Hospital, Oxford Road, Manchester, UK

Introduction: Children admitted to paediatric and neonatal intensive care units (P/NICUs) are at high risk from medication errors (MEs) and preventable adverse drug events (pADEs).

Aim: To systematically review and critically appraise empirical studies examining the prevalence and nature of MEs and pADEs in PICUs and NICUs.

Method: Seven electronic databases were searched (January 2000 to July 2017) as well as the grey literature. Quantitative observational studies published in English reporting rates of MEs or pADEs in children ≤ 18 years of age admitted to PICUs or NICUs were included. Studies were heterogeneous in nature and were presented using ranges or median with interquartile ranges (IQRs).

Results: Thirty-six unique studies were eligible for inclusion, with the majority originating from the United States of America (USA) ($n = 10$, 27.7%) and 21 (58.3%) being published from January 2010 onwards. In PICUs, overall ME rates ranged from 5.7 to 48.8 per 100 medication orders ($n = 3$) and 6.4 to 9.1 per 1000 patient days ($n = 2$). In NICUs, MEs rates ranged from 5.5 to 77.9 per 100 medication orders ($n = 2$) and from 4 to 35.1 per 1000 patient days ($n = 2$). Across both settings prescribing and medication administration errors (P/MAEs) were found to be most commonly associated with MEs and that dosing errors were a common subtype of MEs. Most studies examined PEs ($n = 19$, 52.8%) with a median prevalence of PEs per 100 orders of 13.3 (IQR 9.5–29.55) in PICUs ($n = 12$) and 14.9 (IQR 4.25–29.9) in NICUs ($n = 6$). MAEs occurred in 28.9% of orders ($n = 1$) and 8.2% of administrations ($n = 1$) in PICUs and ranged from 8.2% to 84.8% of administrations in NICUs ($n = 3$). Rate of pADEs in NICUs ranged from 0.47 to 14.38 per 1000 patient days ($n = 2$). A total of three studies in PICUs reported pADEs rates using different denominators.

Commonly involved drugs with MEs or pADEs were anti-infectives, analgesics, and sedatives in PICUs and anti-infectives in NICUs.

Conclusion: MEs are a common problem in PICUs and NICUs. Our review has identified important targets that could help set an improvement agenda for both health care leaders and researchers. There is also a need for research from countries outside of the USA and for future work to explore in more detail outcomes such as MAEs and pADEs that have received limited attention in the current evidence base.

Network meta-analysis to estimate treatment efficacy: The example of venous thromboembolism prophylaxis strategies in major orthopaedic surgeries

D.M. Dawoud¹, S. Lewis², J. Glen², S. Dias³, C. Sharpin²

¹University of Hertfordshire, Hatfield, UK, ²National Guideline Centre, Royal College of Physicians, London, UK, ³University of York, York, UK

Aim: To review and synthesise the evidence from randomised controlled trials (RCTs), which assessed the efficacy of venous thromboembolism (VTE) prophylaxis strategies in people undergoing major orthopaedic surgeries using network meta-analysis (NMA).

Methods: Systematic reviews of randomised controlled trials (RCTs) assessing the efficacy of VTE prophylaxis in elective total hip replacement (eTHR) and elective total knee replacement (eTKR) were undertaken. The following databases were searched: The Cochrane Library (CENTRAL), EMBASE, and Medline. Risk of bias was assessed using The Cochrane risk-of-bias tool. Bayesian NMAs of three outcomes (deep vein thrombosis (DVT), pulmonary embolism (PE), and major bleeding [MB]), for each population, were undertaken using the software WinBugs 1.4.3. The median (95% credible intervals [CrIs]) relative risk (RR) and odds ratio (OR) compared to no prophylaxis, ranks, and probability of being the best were calculated.

Results: For eTKR, rivaroxaban for 14 days had the highest probability of being the most effective in terms of DVT prevention (RR = 0.12, 95% CrI: 0.09–0.56). Low-molecular-weight-heparin (LMWH) at a standard prophylactic dose (40 mg once daily) for 28–35 days ranked first in the pulmonary embolism (PE) network (RR = 0.02 [0.00–3.86]). LMWH at a low-prophylactic dose for 14 days ranked first in the MB network (OR = 0.08 [0.00 to 1.76]).

For eTHR, rivaroxaban for 28-35 days (RR = 0.06, 95% credible 0.29) had the highest probability of being best in the DVT network. A strategy of LMWH at a standard prophylactic dose for 10 days followed by low-dose aspirin for 28 days had the highest probability of being best in the PE (RR = 0.0011 [0.00–0.096]) and MB (OR = 0.37 [0.00–26.96]) networks, respectively.

The PE and MB networks' results were highly uncertain; with very wide CrIs around the median estimates for both eTHR and eTKR.

Conclusion: Pharmacological prophylaxis strategies are more effective compared to mechanical methods in the prevention of DVT, with rivaroxaban ranked higher compared to other strategies. However, this comes at the expense of a possible increase in major bleeding. An outcome measure that reflects the impact of both VTE interval (CrI): 0.01 and bleeding, for example quality of life, would be more appropriate for guiding clinicians' decisions regarding the choice of the optimal VTE prophylaxis strategy.

Disclaimer:

This work was undertaken by the National Guideline Centre (NGC), Royal College of Physicians London, which received funding from the National Institute for Health and Care Excellence (NICE). The views expressed in this publication are those of the authors and not necessarily those of the Institute.

Design and initial testing of a virtual patient as part of a workshop to improve person-centred care

S. Jacklin, N. Maskrey, S. Chapman

School of Pharmacy, Keele University, Keele, Staffordshire, UK

Aim: To develop and test a Virtual Patient (VP) for improving the ability of primary care professionals to consult in a person-centred manner and achieve shared decision-making.

Methods: The VP was designed in a multi-stage process; initial scripting, patient involvement, and expert review. The initial script was written by SJ, NM, and SC. SJ then met with three patients individually to discuss the script and gather their suggestions for improvement. These improvements were then implemented and a prototype VP sent to the expert reviewers. Final changes were subsequently made before the digital creation commenced.

Primary care pharmacists attended a good practice day in October 2017. The day featured a lecture, followed by group analysis of video recorded consultations. After this, the attendees used the VP for around 25 minutes before a whole group debrief. Four case studies were completed by the participants, two at the start of the workshop, two at end. The participants were asked to list three questions or statements they would wish to ask/say to each case study patient. These answers were rated by SJ as either technically-centered, or person-centred; NM second rated them and any disagreement was discussed. A paired t-test in SPSS was used to determine whether any change in the number of patient-centred questions asked before and after the day was significant.

Results: A branched-narrative VP was created that was accessible via a website from a smartphone, tablet, or laptop. The entirety of the consultation was simulated, from introductions and agenda setting through to prescribing treatment, if the latter were required. The scenario focused on whether or not to prescribe a statin for primary prevention, and the patient was represented by autonomous, high-quality animation and voice over. The system provides feedback on the learner's performance designed to encourage repetitive practice, in line with Ericsson's theory of the acquisition of expertise (1993). Thirty-nine pharmacists completed the case study evaluation. 74% of participants asked more person-centred questions at the end of the workshop compared to the start ($n = 29$); this change was statistically significant ($p < 0.0005$).

Conclusion: VPs may facilitate the practice of person-centred consultation skills and shared decision-making. It is unclear which components of the workshop led to the change observed and whether or not it led to a change in real world outcomes. Future research will aim to explore this.

REFERENCES

Ericsson KA, Krampe RT, and Tesch-Römer C. The role of deliberate practice in the acquisition of expert performance. *Psychological review*, 1993, 100(3), p.363

Note: Were this abstract to be presented orally, we would showcase the VP live.

Prevalence and nature of medication errors and medication related harm immediately following hospital discharge from hospital to community settings: A systematic review

*F.A. Alqenae¹, D. Steinke¹, R.N. Keers^{1,2}

¹Centre for Pharmacoepidemiology and Drug Safety, Division of Pharmacy and Optometry, School of Health Sciences, University of Manchester, Manchester, UK, ²Pharmacy Department, Greater Manchester Mental Health NHS Foundation Trust, Manchester, UK

Background: The immediate time period post hospital discharge may be associated with important risks to patient safety. Drug safety problems may occur at or following discharge such as communication issues and medication changes which might manifest into safety risks in the community such as medication errors (MEs) and related harm^{1,2}. Whilst some evidence exists relating to these safety risks at the point of hospital discharge, there is comparatively little known about their burden and nature in the immediate post-discharge period in the community.

Aim: Systematically identify and evaluate the available international evidence on the prevalence and nature of medication errors and medication related harm immediately following transition of care from hospital to community settings.

Methods: The search was carried out between the dates January 1990 and September 2018, using the grey literature and 10 databases, including; MEDLINE, EMBASE, CINAHL, PsycINFO, International Pharmaceutical Abstracts, Health Management Information Consortium, Cochrane Database of Systematic Reviews, Cochrane Central

Register of Controlled Trials, Database of Abstracts of Reviews of Effects, and Web of Science. No restrictions were applied on study language, country, or population. Reference lists of included studies and relevant review articles were also searched to identify relevant citations. Studies were excluded if they focused on single drug, drug class, or disease. Data from each study were extracted independently by two reviewers. Quality assessment of the included studies was completed using a validated framework³.

Results: Sixty-nine studies met the inclusion criteria. Sixteen studies (23%) reported MEs rates, nineteen studies (27.9%) reported rates of unintentional medication discrepancies, twenty-one studies (30.4%) reported adverse drug reactions rates, and twenty-four studies (34.7%) reported rates of adverse drug events (ADEs). A total of 30 (43.4%) studies originated from the in the United States, and 54 (78%); were published from the year 2010 onwards. Twenty-two (32%) studies data about severity of identified outcome measures. The median rate of ADEs was found to be 18.8% (Inter Quartile Range [IQR] 14–29) ($n = 23$) and the median rate for MEs was found to be 33% (IQR 19–52) ($n = 14$) for adult and elderly patients. Heterogeneity was observed in the included studies in terms of outcome definitions and data collection methods, which precluded meta-analysis. The most commonly reported medications associated with post hospital discharge ADEs were antibiotics, antidiabetics, analgesic medications, and cardiovascular drugs.

Conclusion: Medication errors and medication related harm are common immediately following transition of care from secondary to primary care. Standardisation of study design is an important target for future research to reduce heterogeneity. Despite this, a number of important targets were identified for future research that could guide the development of successful remedial interventions.

REFERENCES

1. Forster A, Murff H, Peterson J, et al. "Adverse drug events occurring following hospital discharge". *J Gen Intern Med*. 2005; 20(4): 317–323.
2. Mixon A, Myers A, Leak C, et al. "Characteristics associated with post discharge medication errors". *Mayo Clin Proc* 2014; 89(8): 1042–1051.
3. Allan E, and Barker K. "Fundamentals of medication error research". *Am J Hosp Pharm*. 1990; 47(3): 555–571.

Identifying indicators of potentially hazardous prescribing related to mental health disorders and medications: A systematic review

*W. Khawagi^{1,2}, D. Steinke¹, J. Nguyen^{1,3}, R. Keers^{1,3}

¹ Division of Pharmacy and Optometry, School of Health Sciences, Faculty of Biology, Medicine and Health, University of Manchester, Manchester, UK, ² Clinical Pharmacy Department, College of Pharmacy, Taif University, Taif, Kingdom of Saudi Arabia, ³ Pharmacy Department, Greater Manchester Ment Health NHS Foundation Trust, Manchester, UK

Background: Measuring the safety of prescribing is vital to understanding and improving patient care. As a result, several sets of hazardous prescribing indicators and criteria have been developed for use across primary and secondary care settings. Despite the fact that

prescribing errors and medication-related harm may be common in patients with mental illness, there has been limited research focusing on the development and application of potentially hazardous prescribing indicators, known as prescribing safety indicators (PSIs), specifically for this unique patient group.

Aim: Identify existing indicators of potentially hazardous prescribing related to mental health (MH) medications and conditions from the published literature.

Methods: A systematic search was conducted using seven electronic databases: Embase, MEDLINE, PsycINFO, Web of Science, HMIC, IPA, and CINAHL (from 1990 to November 2017). The bibliographies of included studies and of relevant review articles were reviewed for additional studies. Citation screening followed three phases; first, studies which developed, validated or updated a set of explicit medication-specific indicators or criteria that measured prescribing in terms of safety or quality were eligible for inclusion, irrespective of whether they contained MH indicators or not. Second, relevant articles underwent further screening to extract any MH-related indicators (quality or safety), which was determined based on our operational definition. Finally, two expert MH clinical pharmacists screened the identified MH indicators and selected PSIs that described potentially hazardous prescribing that could cause significant risk of harm. These PSIs were categorised into seven prescribing problems and nine medication categories.

Results: Seventy-six unique studies were included, 67 of which contained at least one MH-related indicator along with five that specifically focused on indicators for populations with mental illness. Among the 67 studies containing MH indicators, the elderly population was the most commonly targeted ($n = 36$, 53.7%), and the most common method for indicators validation was the Delphi method ($n = 32$, 47.8%). A total of 1262 MH prescribing indicators were identified, with an average of 18 (SD = 24.7) per study (range 1–127); 245 of these were considered PSIs. Among the identified PSIs, the most common type of prescribing problem was "Potentially inappropriate prescribing considering diagnoses or conditions" ($n = 106$, 43.3%), and the lowest was "omission" ($n = 6$, 2.4%). "Antidepressant" was the most common medication category ($n = 85$, 34.7%) and "non-specific psychotropics" was the lowest ($n = 1$, 0.4%).

Conclusion: This is the first systematic review to identify a comprehensive list of MH-related indicators of potentially hazardous prescribing. Examination of the types of indicators reported has revealed important targets for new PSIs and will inform the development of a new expanded suite of PSIs applicable to patients with mental illness.

Examining medication safety incidents in in-patient mental health settings: A 7-year analysis of incidents reported to the National Reporting and Learning System

G.H. Alshehri¹, R.N. Keers^{1,2}, J. Nguyen², A. Carson-Stevens⁴, D.M. Ashcroft^{1,3}

¹ Centre for Pharmacoepidemiology and Drug Safety, Division of Pharmacy and Optometry, School of Health Sciences, University of Manchester, Manchester Academic Health Sciences Centre (MAHSC),

Manchester, UK, ²Pharmacy Department, Greater Manchester Mental Health NHS Foundation Trust, Manchester, UK, ³NIHR Greater Manchester Patient Safety Translational Research Centre, Manchester Academic Health Sciences Centre (MAHSC), University of Manchester, Manchester, UK, ⁴Division of Population Medicine, School of Medicine, Cardiff University, Cardiff, United Kingdom

Background: Medication-related problems are recognised as important patient-safety issue in mental health hospitals.(1) Based on our systematic review of 20 studies, the frequency of medication errors and adverse drug events ranged from 10.6 to 17.5 and 10.0 to 42.0 per 1000 patient-days, respectively.(2) In 2006, the National Patient Safety Agency (NPSA) published a report examining medication safety incidents originating mental health hospitals as reported to the National Reporting and Learning System (NRLS) from 2003 until the end of September 2005.(1) Whilst informative, this report is now outdated and the medication incidents reported were not analysed extensively in term of their nature, location and severity. The present study, however, presents updated and more extensive review of medication incidents over a 7-year period.

Aim: To describe the nature and severity of medication safety incidents reported within mental health hospitals across England and Wales between 2010 and 2017.

Method: A retrospective review was carried out of all medication safety incidents submitted from in-patient mental health units to the NRLS between 2010 and 2017. A descriptive analysis was undertaken to determine the number of medication incidents over time, and then to characterise the incidents according to their nature, location, severity and type of medication class involved. The University of Manchester's Ethics Committee has exempted this study from formal ethical approval.

Result: A total of 94,159 medication incident reports were included, the majority of which were due to medication errors (93,722; 99.5%). Ninety percent (85,099; 90.3%) originated from in-patient mental health services: mental health wards (71,993;76.5%), secure units (11,149;11.8%), intensive care units (1,870;1.9%) and electro-convulsive therapy unit (87;0.09%). Medication incidents from mental health pharmacy services accounted for 6.4% (n=6,055) of the reports. The type of inpatient mental health settings was not specified in 0.66% (n=623) of the reports or left blank by the reporter (2,382; 2.5%) Medication incidents occurred most frequently in the administration stage (50,310; 53.4 %), followed by the prescribing (15,549;16.5%) and dispensing (10,875; 11.5%) stages. Omitted medicine (17,210;18.2%), followed by wrong frequency (11,860;12.6%) and wrong/unclear dose (10,251; 10.8%) were the types of medication errors most frequently reported. Medicines from central nervous system were commonly reported (42,760; 44.3%) including antipsychotics (15,053; 35.17%), followed by anxiolytics/hypnotics (8,141; 19.0%) and antidepressant (5,791; 13.53%). The clinical outcome analysis of the medication incidents demonstrated that 98.4% (n= 84,252) of incidents resulted in no harm, whereas the remaining incidents resulted in low harm (8,787;9.3%), moderate harm (1,076;1.1%), severe harm (41; 0.04%), or death (4, 0.004%).

Conclusion: Our findings suggest that a tenth of medication incidents reported in mental health hospitals resulted in harm to patients. Fifty percent of incidents occurred in the medication administration stage, with medication omission and antipsychotics being frequently

implicated. Further in-depth analysis to understand the contributory factors associated with these incidents is needed to improve medication safety in this setting.

REFERENCES

1. National Patient Safety Agency. With safety in mind: mental health services and patient safety.2006. <http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60040&>.
2. Alshehri GH, Keers RN, Ashcroft DM. Frequency and Nature of Medication Errors and Adverse Drug Events in Mental Health Hospitals: a Systematic Review. *Drug Safety*. 2017;40(10):871–86.

Switching anticoagulation treatment during inpatient stay—does it occur routinely?

M. Wilcock¹, E. Dryden¹, L. Kelly¹, J.Y. Khoo²

¹Pharmacy Department, Royal Cornwall Hospitals NHS Trust, Truro, UK,

²3rd year pharmacy student, University of Nottingham, Nottingham, UK

Background: Anticoagulants (oral, injectable) are used for a variety of indications with direct oral anticoagulants (DOACs) increasingly used instead of warfarin in non-valvular atrial fibrillation (NVAF) and venous thromboembolism. Switching from warfarin to a DOAC in NVAF has been described in a primary care setting.¹ We wished to investigate an observation from a GP that patients with NVAF admitted into hospital on warfarin were being discharged home on a DOAC.

Aim: To utilise Hosp electronic prescribing system (EPS) to identify patients admitted on warfarin and to ascertain which, if any anticoagulant, they were discharged on, and to understand the rationale for any patients with NVAF who had their anticoagulant switched.

Methods: Data on patients prescribed warfarin on day 1 or 2 of their admission and who were discharged over 12 months to end of May 2018 were extracted from our EPS. This extract also identified the anticoagulant prescribed on the discharge prescription. Discharge letters and the medical notes for a subset of patients with NVAF were examined. Data were analysed using Microsoft Excel. This study did not require ethics approval.

Results: There were 1,105 episodes of warfarin prescribed at admission, of which 261 (24%) were discharged on no anticoagulant, 691 (63%) on warfarin alone, 92 (8%) on warfarin plus low molecular weight heparin, and 61 (6%) discharged on an anticoagulant other than warfarin.

It is assumed that the majority of those without an anticoagulant on their discharge prescription either had the drug temporarily withheld whilst an inpatient or had a short hospital stay and so warfarin was not recorded on their discharge prescription.

Of those discharged on a DOAC alone (38 episodes), a diagnosis of NVAF at admission was clear in 17 cases (mean age 78 years, range 62 to 92).

Medical records were available for 12 of these patients. In 7/12 records, the switch from warfarin to a DOAC was deemed reasonable, e.g. patient described as confused and unable to manage warfarin/INR testing; patient also on dual antiplatelet therapy; and two instances of a discussion with the patient about the switch to DOAC documented

in the discharge letter. In 5/12 records, it was not obvious why the switch had occurred.

In those five cases where medical records could not be scrutinised, it was not clear in the e-discharge letter why the switch had occurred.

Conclusion: Though we examined in detail those patients with NVAf whose anticoagulant had been switched, in total, there were only 6% (61/1105) patients admitted on warfarin for a variety of indications discharged on a different anticoagulant. We conclude there was no evidence of a routine policy to switch inpatients with NVAf on warfarin to a DOAC. However, when patients are switched, documentation in the e-discharge letter as to the reason for the switch was not explicit in 10/17 (59%) cases.

This study focused on a small subset of patients whose warfarin was switched and results may not be generalizable.

REFERENCES

1. Fosbøl EL, Vinding NE, Lamberts M, Staerk L, et al., 'Shifting to a non-vitamin K antagonist oral anticoagulation agent from vitamin K antagonist in atrial fibrillation', *Europace*. 2018; **20**(6):e78-e86.

An audit of the use of direct oral anticoagulants in the Mercy University Hospital

A. Fleming¹, C. Halleran², E. Cagney²

¹Pharmaceutical Care Research Group, School of Pharmacy, University College Cork, Ireland, ²Department of Pharmacy, Mercy University Hospital, Cork, Ireland

Introduction: The introduction of direct oral anticoagulants (DOACs) has changed the landscape of anticoagulation with widespread clinical use, replacing warfarin in many cases. However, they are not without risk and inappropriate use (IU) with risk to patient safety has been highlighted¹.

Aim: To determine the appropriateness of DOAC usage, and the factors influencing prescribing, in the Mercy University Hospital (MUH) Cork, Ireland.

Methods: A prospective, observational cohort study was conducted from 1 December 2016 to 31 May 2017, on a sample of medical and surgical wards in MUH. DOAC prescriptions for venous thromboembolism (VTE) or atrial fibrillation (AF) were included. Patients post hip or knee replacement were excluded. Prescriptions were reviewed for appropriateness in accordance with prescribing criteria in the drug summary of characteristics; indication, dose, frequency, duration, renal function, drug interactions, and contraindications. Qualitative semi-structured, interviews were conducted with MUH doctors and pharmacists in June 2017. Ethical approval was obtained and interview participants provided written informed consent.

Results: A total of 159 DOAC prescriptions were reviewed (72.3% male patient prescriptions). The median patient age was 76 years (IQR 70–82 years). The most commonly prescribed DOAC was apixaban (50%, $n = 79$), followed by rivaroxaban (41%, $n = 66$), dabigatran (7%, $n = 11$), and edoxaban (2%, $n = 3$). The majority of prescriptions were prescribed for AF (81%, $n = 129$), then VTE (17%,

$n = 27$), with some cases of unlicensed use (2%, $n = 7$). In total, 72% ($n = 114$) of all DOAC prescriptions were inappropriate. This inappropriate prescribing reached 57.9% ($n = 92$) of patients and were intervened on by the ward pharmacist. The highest proportion of IU was due to sub-therapeutic dose (31.6%, $n = 32$) or supra-therapeutic dose (24.6%, $n = 28$). DOAC prescriptions where there had been transition from another anticoagulant (eg, low molecular weight heparin) were inappropriate in 19.3% of cases ($n = 22$). Drug interactions occurred in 14% ($n = 16$) of prescriptions. There was a significant proportion of apixaban deemed inappropriate ($X^2 = 5.48$, $p = 0.019$).

Fourteen interviews were conducted (11 doctors, three pharmacists), ranging in length from 4 to 21 minutes. Doctors reported their preference for prescribing DOACs over warfarin due to reduced therapeutic drug monitoring and the availability of an antidote for one DOAC. Participants reported the transition between one type of anticoagulant to a DOAC as a high-risk period for under or over anticoagulation. Doctors reported the need for prescribing workshops and clear guidelines, especially for the peri-operative period.

Conclusion: This study revealed a high level of inappropriate DOAC use in our hospital and underlines the importance of clinical pharmacist prescription screening to prevent serious harm arising from inappropriate prescribing. Our findings highlight the need for clear and accessible training opportunities and guidelines for prescribers, as well as regular clinical audit and feedback to improve practice.

REFERENCES

1. Irish Medication Safety Network. Safety Alert Direct Oral Anticoagulants <http://www.imsn.ie/all-news/20-alerts/35-doacs>. (Accessed 5th September 2018).

The contribution of digital technology in supporting older people manage their medicines

K. Warmoth, J. Frost, N. Britten

University of Exeter, Exeter, England

Background: With an ageing population, the concurrent use of multiple medicines, or polypharmacy, is increasing. Multiple medicines and conditions can have a considerable impact on an individual, and between one-half and one half of all medication prescribed for long-term conditions is not taken as recommended.¹ Supporting community-dwelling older people to manage their multiple medicines is therefore imperative. **Aims:** This review identifies and assesses which tools or resources are available for older people to manage multiple medicines or complex treatment regimens.

Methods: A scoping review² was conducted. Electronic databases (MEDLINE and CINAHL), grey literature, select paper citations, conference presentations, Cochrane Database of Systematic Reviews, and key author publications were iteratively searched. English-language studies that included medicines self-management tools were eligible. Data extracted from included articles were categorised on the basis of their utility, and the similarities and differences between tools were mapped.

Results: One hundred nineteen articles met our inclusion criteria and are included in the review. Findings suggest that, firstly, most tools are developed to ensure adherence—not medicine optimisation. Secondly, there has been a considerable growth in the development of digital technology for medicines management in the last decade. Lastly, it is unclear whether such tools are supporting medicines optimisation or mere adherence.

Conclusions: This review outlines the tools or resources, which may be useful for older people to self-manage multiple medicines, the evidence for the use of different tools, and gaps in knowledge for further research. It also questions the contribution of digital technology in supporting older people to manage their medicines. Evidence about such tools is warranted so that older people can maximise the use of their medicines, and consequently reduce the societal costs of the inappropriate use of medicines.

REFERENCES

1. National Collaborating Centre for Primary Care and Royal College of General Practitioners Clinical Guidelines and Evidence Review for Medicines Adherence: Involving patients in decisions about prescribed medicines and supporting adherence (2009). Nunes V, Neilson J, O'Flynn N, *et al*.
2. Arksey, H., & O'Malley, L., "Scoping studies: towards a methodological framework", *International Journal of Social Research Methodology*, 2005; 8(1): 19–32.

Oral dosage form (ODF) modifications for older adults: A direct observation of practice in aged care facilities in Ireland

*L.J. Sahm, A.M. Crean, M. Kelly, A. Mc Gillicuddy

Background: ODF modifications (e.g. crushing or splitting tablets) can potentially affect drug safety and efficacy; however, this is dependent on factors including the medication, the dosage form, the method of modification, and the subsequent method of administration. There are a lack of data describing ODF modifications, particularly the methods of modification and administration. In order to identify priority areas for intervention, there is a requirement for a thorough investigation of current ODF modification practices.

Aim: The aim of this study was to elucidate ODF modification and administration practices in aged care facilities (ACFs) in Ireland using undisguised, direct observation of drug rounds.

Methods: Undisguised, direct observations of medication administration to older patients on 13 wards in five ACFs in Ireland was undertaken between May 2017 and July 2018. Patients who met the following criteria were eligible to be included in the study: (1) resident in the ACF; (2) aged ≥ 65 years; (3) received medication from nurses during drug rounds; and (4) written, informed consent for inclusion was provided (by the patient or their next-of-kin if the patient lacked the capacity to consent). Demographic and medical details about included patients were recorded from the patients' medical records. The drug round observations were undertaken by one researcher who recorded details including: the name, dose, dosage form, route,

and method of administration of medication, as well as details of any ODF modifications.

Results: Medicine administration to 141 patients (63.8% female, mean age [SD] 83.96 years [7.26]) was observed. In total, 44.7% of patients received at least one modified solid ODF during the observed drug rounds. Amongst patients who received modified medicines, 46.0% had medicines modified to overcome swallowing difficulties, 41.3% to facilitate fractional dosing, and 12.7% required medicines to be modified for both reasons. One hundred seventy-eight instances of modification were observed for 71 different medications, with drugs acting on the Central Nervous System the most commonly modified. Of these 178 modifications, 81.5% were unlicensed, and just under half of these unlicensed modifications were authorised in the best practice guidelines. Modified medicines were most frequently administered using food vehicles or thickened fluids, while almost one fifth of non-modified solid ODFs and liquid ODFs were administered with thickened fluids or in food vehicles.

Conclusions: This study has provided important insights into ODF modification and administration practices in ACFs in Ireland. ODF modifications are commonly required to tailor oral medicines to meet the swallowing capabilities and dosing requirements of older adults. Whilst, many of the modifications were not authorised in either the product licence or best practice guidelines, the majority of administration practices were optimised within the limitations of current marketed formulations. Further research is needed to optimise medication formulation suitability for older adults and the findings of this study, by describing the current reality of medication administration, should inform the direction of this research.

Improving pain management in patients with a fractured neck of femur

M. Serag, E. Lim, L. Henderson

Northumbria Healthcare NHS Foundation trust, Cramlington, UK

Introduction: Patients with a fractured neck of femur (#NOF) are often not prescribed rational or adequate analgesia post-operatively. Patients experiencing pain are slower to mobilise and have poorer health-related quality of life. This quality improvement initiative, as part of the HIPQIP Scaling Up Improvement Programme, describes a multidisciplinary approach to improving pain management in these patients with anticipated benefits on earlier mobilisation and length of stay.

Objective: To evaluate the progress and compliance of prescribers with a standard analgesic prescribing regime as part of the fracture neck of femur enhanced recovery pathway, and how this affects mobilisation and length of stay.

Methods: In November 2016, a standardised, analgesia regime incorporating regular and when required oxycodone was agreed by the multidisciplinary team. Analgesia prescribing and impact on mobilisation pre- and post-implementation was audited to assess effectiveness. A 10-patient re-audit took place in December 2017 to evaluate compliance with the prescribing protocol. A pre-printed medication chart was introduced in January 2018, to encourage further standardisation.

A monthly rolling audit from February 2018 onwards was subsequently commenced.

Time to mobilisation and its impact on length of stay pre and post-standardisation during these periods was also assessed as part of this evaluation.

Results: Prior to establishment of an agreed protocol, there was a wide variation in choice of analgesics and schedules prescribed. Variation reduced following agreement of a standardised regime, achieving 70% compliance Day 1 post-op. Launch of a pre-printed chart improved standardisation with 100% compliance on Day 1 for 4 out of the next 5 months. Introduction of electronic prescribing reduced compliance initially to 50% due to unfamiliarity with the system, transcribing errors from paper chart to electronic system, and the initiation of newly qualified doctors in August 2018. In September 2018, compliance had begun to return towards pre-electronic prescribing rates at 80% on Day 1 post-op.

In addition, mobility was shown to improve with 100% patients being able to mobilise Day 1 post-op, an increase from 91%. The proportion of patients mobilising with a zimmer frame increased from 43% to 71.5%, with the number mobilising with a zimmer frame either independently or more than 5 metres with support, increasing from 13% to 50.5%. This was accompanied by a reduction in length of stay from 22.5 days pre-standardisation to 18.1 days post-standardisation.

Conclusion: Introduction of a standardised pain protocol has been achieved by working closely with all members of the multi-disciplinary team. Pre-printing onto a medication chart ensured compliance across all prescribers. Electronic prescribing has introduced challenges in compliance with the protocol which should improve with familiarity with the system. The revised protocol has led to improvements in early mobilisation. Overall, the HIPQIP programme has demonstrated a reduction in mortality from 8.1% to 4.9% and reduction in length of stay to which this work may have contributed.

Evaluation of polypharmacy reviews in primary care

Introduction: Inappropriate polypharmacy, especially in older people, imposes a substantial burden of adverse drug events, ill health, disability, hospitalisation, and even death.¹ To help address this, the local CCG asked its general practices to conduct polypharmacy reviews (PR) on 2% of their patient list, incentivised by a payment per patient.

Aim: The aim of this evaluation was to determine the number and quality of PRs conducted by general practices and the resulting change in repeat templates prescribed.

Method: Each general practice's SystemOne records were searched for the period 1 April 2017 to 31 March 2018 to identify all patients with a PR code. A detailed review of up to 10% of PRs for each general practice was completed by an experienced pharmacist. Anonymous demographic and descriptive data were recorded for all patients and summarised using summary statistics in Microsoft Excel (2010). Sampled PRs were categorised according to review quality: good (no additional actions identified), adequate (additional cost saving or minor clinical issues identified), inadequate (additional major

clinical issues identified), and not actioned (no recommended actions taken) by the reviewing pharmacist.

Results: 5671 (198%) of a target of 2869 polypharmacy reviews were conducted between 1 April 2017 and 31 March 2018. Table 1 shows the mean age of patients reviewed and median number of repeat templates were similar across localities. The median change in number of repeat templates and quality of PRs varied across localities, but would equate to a 3752 reduction in repeat templates for all patients with a PR.

Conclusion: Despite the ongoing workforce crisis, general practices exceeded their PR targets with good and adequate reviews. These reviews produced substantial reductions in repeat templates across the area. Financial incentives for practices to conduct PRs can be successful in tackling inappropriate polypharmacy.

REFERENCES

Scottish Government Polypharmacy Model of Care Group. *Polypharmacy Guidance, Realistic Prescribing 3rd Edition*, 2018. Scottish Government

Evaluation of enhanced clinical pharmacy service on older peoples wards

C. Barnes, T. Miller, C. Rezwana, A. McClean

Pharmacy Department, Northumberland, Tyne and Wear NHS Foundation Trust, Newcastle Upon Tyne, UK

Aims/Objectives: Difficulties in recruiting medical staff led to skill mix review and initial rollout of extended pharmacy service on older people's wards in line with medicines optimisation agenda and CQC Key lines of enquiry.

The aim of the service was:

1. To release medical staff time by providing an enhanced pharmacy service.
2. To improve the quality of patient care by increased medicines optimisation.

Methods: Two specialist clinical pharmacists were recruited to work on two wards for 37.5 hours per week. In addition to NTW clinical pharmacy service standards, the roles undertaken were:

- Transcribing all leave and discharge prescriptions.
- Transcribing all medication charts.
- Updating patient electronic medication records and related assessments.
- Increased input at all stages of the patient journey.
- Increased contact with patients/carers for medication issues.
- Integrating with the MDT attending all meetings including the 72 hour and discharge meetings, improving quality and quantity of clinical interventions.
- Medicine optimisation at the interface of care.

TABLE 1 Summary of patient and polypharmacy review (PR) characteristics for different localities

| | | Locality 1 | Locality 2 | Locality 3 | All Localities |
|--|--------------|------------|------------|------------|----------------|
| PR target | | 1164 | 863 | 843 | 2869 |
| No. PRs conducted (% PR target) | | 2875 (247) | 1582 (183) | 1214 (144) | 5671 (198) |
| Mean age patient with PR | | 76 | 71 | 74 | 74 |
| Median (IQR) repeat templates at evaluation | | 8 (5, 11) | 9 (5, 13) | 9 (6, 12) | 8 (5, 12) |
| No. (%) PR sampled | | 159 (6) | 142 (9) | 101 (8) | 402 (7) |
| Change in no. repeat templates per patient following PR | | −0.3 | −0.9 | −0.9 | −0.7 |
| Number (% of reviewed PRs) categorised as: | Good | 44 (28) † | 58 (41) † | 15 (28)* † | 117 (33) † |
| | Adequate | 89 (56) † | 60 (43) † | 30 (57)* † | 179 (51) † |
| | Inadequate | 22 (14) † | 8 (6) † | 4 (8)* † | 34 (10) † |
| | Not actioned | 4 (3) † | 15 (11) † | 4 (8)* † | 23 (7) † |
| Estimated no. (% of target PR) or good/adequate quality for all patients | | 2405 (207) | 1324 (153) | 1031 (122) | 4755 (166) |

Abbreviations: PR, polypharmacy review; IQR, interquartile range. *Quality of PR was not evaluated for two practices due to a conflict of interest with the reviewing pharmacist and to maintain anonymity of the practices; †Percentages total > 100% due to rounding.

Data was collected over a 3 and 6 month period to evaluate the increased service.

Results

Approximately 8 hours doctors time was saved per week through writing of all leave and discharge prescriptions, rewriting charts, updates to electronic medication records throughout the patient journey in addition to other medicines optimisation tasks that would have previously been completed by a doctor.

1. Clinical interventions per patient (taken from entries on electronic care record in this time period) increased 5 fold on average per patient for both wards. This reflects the extra clinical pharmacy input, contributions to patient care and patient interactions.
2. Medicines reconciliation completed for 100% patients (average trust-wide is 87%).

Overwhelmingly positive feedback received from ward teams, including medical staff

Conclusion: The success of the enhanced service has led to it being rolled out to adult acute wards within the locality and potentially other OPS wards Trust wide. Also, to review how skill mix can be further embedded to utilise the skills of other pharmacy team members within the service and pharmacist prescribing.

Assessment of the impact of a clinical pharmacy service in the emergency department of an acute teaching hospital in Ireland

T.M. Barbosa¹, E. Relihan³, G. Melanophy², L. Keaveney^{1,2}

¹School of Pharmacy, University College Cork, Cork, Ireland, ²Pharmacy Department, St. James's Hospital, Dublin, Ireland, ³Medication Safety St. James's Hospital, Dublin, Ireland

Background: The Emergency department (ED) is recognised as a high-risk environment for patients¹. Medication errors occurring in the ED

have the potential to impact patient's safety throughout their inpatient stay². Research is needed to determine the contribution of clinical pharmacists in ED in Ireland.

Aim: To investigate the impact of introducing an ED clinical pharmacy service by establishing the: (1) volume and type of clinical pharmacist's activities in relation to medication reconciliation and clinical review; (2) cost avoidance attributed to interventions; and (3) timing of pharmacist encounter with patients in the ED in comparison to standard care.

Methods: Adult patients aged over 65 years, admitted via the ED, were eligible for inclusion. Medication reconciliation was provided by the clinical pharmacist, and a complete clinical review of the patient's medication was undertaken. Medication discrepancies and additional medication concerns were communicated to the relevant medical teams. The clinical significance of these interventions was scored by a peer review panel using a validated tool.

Results: Sixty patients were included in this study, of which 82% required at least one clinical pharmacist intervention. One hundred forty interventions were undertaken by the clinical pharmacist, i.e. 2.33 interventions per patient (range 0–8). The majority of interventions (88%) were accepted by medical staff. Upon peer review analysis, 38% of interventions were deemed to have the potential for “minor harm,” 59% of the interventions were deemed to have potential for “moderate harm,” 1% were considered to have the potential for “severe harm,” and the remaining 2% were considered to cause “no harm” to the patient. Cost analysis demonstrated a cost avoidance of €10,131.71. The introduction of an ED pharmacist resulted in patient reviews occurring, on average, 27 hours earlier than standard care.

Conclusion: This analysis demonstrated the benefits, in relation to both patient safety and cost savings, of an ED-based clinical pharmacy service.

REFERENCES

1. Cohen V, Jellinek SP, Hatch A, et al. 'Effect of clinical pharmacists on care in the emergency department: a systematic review', *Am J Health Syst Pharm*, 2009; **66**(15):1353–1361.
2. Heining-Rothbucher D, Bischofberger S, Ulmer H, Pechlaner C, et al., 'Incidence and risk of potential adverse drug interactions in the emergency room', *Resuscitation*, 2001; **49**(3):283–288.

Venous thromboembolism prophylaxis prescribing in renal impairment and extremes of body weight

L.A. Ritchie, A.J. Basey, C. Lee

The Royal Liverpool and Broadgreen University Hospitals NHS Foundation Trust, Liverpool, UK

Introduction: Hospital-acquired venous thromboembolism (VTE) accounts for 50%-60% of all VTE and treatment is associated with a considerable cost¹. The Trust policy recommends dalteparin 5000 units subcutaneously (SC) daily for all eligible medical patients². In those with a creatinine clearance (CrCl) <30 ml/min, a dose of 2500 units SC daily is recommended; in practice, estimated glomerular filtration rate (eGFR) is used². The Trust policy makes no recommendations for weight-based dosing and neither does NICE.^{1,2} Interestingly, the Haemostasis Anticoagulation and Thrombosis (HAT) Committee recommends weight-based dosing (Table 1)³.

Aim

1. To determine whether patients are prescribed prophylactic dalteparin in line with Trust policy.
2. To identify any weight-based prescribing of prophylactic dalteparin, as per recommendations by the HAT Committee.

Methods: Raw data (including age, gender, hospital number, eGFR, weight, and dalteparin dose or reason if not prescribed) were collected retrospectively from 16 medical wards over five working days.

Results:

Renal function

There were 184 patients (92%) prescribed an appropriate dose of dalteparin in line with Trust policy, 169 patients with an eGFR >30 ml/min/1.73m² were prescribed dalteparin 5000 units daily, and 15 patients with an eGFR <30 ml/min/1.73m² were prescribed dalteparin 2500 units daily.

Body weight

There were 5 patients (25%) weighing <50 kg with an eGFR >30 ml/min/1.73m² prescribed dalteparin 2500 units daily. There were 12 patients weighing >100 kg with an eGFR >30 ml/min/1.73m², none were prescribed a weight-based dose.

Conclusion: Most patients were prescribed a standard dose of prophylactic dalteparin in line with Trust policy. There was some evidence of weight-based prescribing in patients weighing <50 kg but not in patients >100 kg, highlighting variability in prescribing practice. There is a risk of underdosing (in overweight and obese patients) and overdosing (in underweight patients) if standard doses of dalteparin are used as body

fat can affect the volume of distribution of dalteparin.⁴ Guidance on when to use weight-based dosing is needed in order to standardise practice and optimise the efficacy and safety of VTE prophylaxis prescribing.

REFERENCES

1. National Institute for Health and Care Excellence. Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism. London. NG89. March 2018.
2. Prevention of thromboembolism (VTE) Policy [77]. The Royal Liverpool and Broadgreen University Hospitals NHS Foundation Trust Formulary. October 2015.
3. What doses of low molecular weight heparins or direct oral anticoagulants are appropriate for thromboprophylaxis for adults at extremes of body weight? HAT Committee, UK Clinical Pharmacy Association. Leicester. October 2015.
4. UKMi medicines Q&A. What factors should be considered when using LMWH to treat venous thromboembolism in patients with high body weight? <https://www.sps.nhs.uk/articles/what-factors-should-be-considered-when-using-lmwh-to-treat-venous-thromboembolism-in-patients-with-high-body-weight/> (Accessed 9th October 2017).

Use of CLOPIXOL ACUPHASE® (ZUCLOPENTHIXOL acetate) on the inpatient care wards within Northumberland Tyne and Wear (NTW) NHS FOUNDATION trust

R. Ayre, C. Thomas, M. Morsy

Northumberland, Tyne and Wear NHS Foundation Trust, Newcastle Upon Tyne, UK

Aims/Objectives

The main objectives of the audit were to:

- Determine if the prescribing of Acuphase® was consistent with its licenced indications.
- Determine if the rationale for prescribing Acuphase® was documented in the patient record (RiO) and if this was in line with the NTW policy.
- Determine if monitoring was undertaken post Acuphase® administration in line with the NTW policy.
- Compare the use of Acuphase® across NTW, identifying any differences in clinical practice needing further investigation.

There was limited assurance of compliance with the audit standards for the use of Acuphase®:

- 97% of prescriptions were compliant with licenced indications for the prescribing of Acuphase®, but two patients received greater than the licenced maximum dose over the 14-day treatment period.
- 35% of patients did not have the rationale for use of Acuphase® documented; 28% were in accordance with Trust policy.
- Only 10% received complete monitoring as required by the Trust policy.
- One area of the trust accounted for 62% of the prescribing of Acuphase®.

TABLE 1 Weight-based dosing recommendations for prophylactic dalteparin

| | <50 kg | 50-100 kg | 100-150 kg | >150 kg |
|------------|------------------|------------------|------------------------|------------------------|
| Dalteparin | 2500 units daily | 5000 units daily | 5000 units twice daily | 7500 units twice daily |

- 75% of patients were accepting regular or PRN oral medication on the day of Acuphase® administration.
- Three patients received Acuphase® who were naive to antipsychotic treatment.

A medical review of the patient before a dose was prescribed only occurred in 50% of the administrations of Acuphase®.

Conclusions: Significant variations were found in the prescribing, administration, and monitoring of Acuphase, and an improvement is required. The audit results have been disseminated and discussed at all levels of the trust. Awareness and training are occurring for all members of the clinical team and specific clinical guidance on the use of Acuphase to meet prescribing, and good clinical practice standards have been developed in collaboration with key prescribers identified by the audit. A re-audit on the use of Acuphase will occur after implementation of the clinical guidance.

The impact of a ward-based pharmacy technician service in an IRISH hospital

E. Lynch¹, J. O'Flynn^{1,2}, C. O'Riordan², C. Bogue², D. Lynch², S. McCarthy^{1,2}, K. Murphy¹

¹School of Pharmacy, University College Cork, Cork, Ireland, ²Pharmacy Department, Cork University Hospital, Cork, Ireland

Introduction or Background (if relevant): Pharmacy technicians have been employed in hospital settings for many years, but only recently have their role been reviewed for potential expansion. Hospitals across Australia, the United Kingdom, and many other countries have implemented a ward-based pharmacy technician service (1, 2), but this is yet to become common practice in Ireland. At present, there is only one published study on the development of the clinical role of pharmacy technicians in Ireland (3).

Aim: The aim of this study was to determine if the expanded role of the ward-based pharmacy technician role could have a positive impact on medicine management systems within a hospital ward.

Methods: This study was carried out over 8 weeks in an Irish hospital. Sixteen wards were studied; four "intervention wards" which have the ward-based technician service in situ, and 12 "control ward" which currently do not. Medicine management systems were assessed within these wards with respect to (1) the presence of excess non-ward stock on drug trolleys, (2) the presence of expired medication on drug trolleys, and (3) the time taken by nurses to complete drug rounds.

Results: The total cost value of the excess non-stock items found on the intervention wards was €97.51 (the average cost per ward was €24.38). The total cost value of the excess non-stock items found on the control wards was €13,767.76 (the average cost per ward was €1,147.31). Eight expired medications were found on the control wards; none were present on intervention wards. The ward-based technician service reduced the average nursing time to complete drug rounds on a per-patient basis by 28%.

Conclusion: This study has demonstrated that the expanded role of the ward-based pharmacy technician has had a positive impact in

several ways; a reduction in the cost of non-stock items present on the ward along with a reduction in expired stock present. Time taken to complete drug rounds was less on the intervention wards compared to control wards, thus, freeing up time for nurses to engage in other patient activities. Further studies should consider the full economic costing of the ward-based pharmacy technician service.

REFERENCES

1. Soma N, Telford J. Comparing the role of pharmacy technicians in the US and UK. *The Pharmaceutical Journal*. 31 Aug 2005.
2. Elliott RA, Perera D, O'Leary K. National Survey of clinical pharmacy services and pharmacy technician roles for subacute aged-care inpatients. *Journal of Pharmacy Practice and Research* 2012(42):125–128, 2.
3. O'Byrne J. *Tallaght Hospital Pharmacy Ward Based Technician Service eHealth Ireland: HSE*; 2015

Reducing the stigma in mental health through shared learning—An evaluation of a joint acute and mental health trust event

A. Young¹, K. Smith², C. Thomas¹, R. Copeland²

¹Pharmacy Department, Northumberland Tyne and Wear NHS Foundation Trust, ²Pharmacy Department, Northumbria Healthcare NHS Foundation Trust

Aims/Objective: To analyse the success and usefulness of the event and whether it would change practice going forward to improve patient care.

Method: An informal evening session was organised by respective workforce leads within the two departments. It was decided to offer refreshments and do the learning through facilitated case studies whereby both patients' mental and physical health needs were reviewed. For example, we looked at dementia and the use of antipsychotics in delirium, lithium, and acute kidney injury, clozapine in someone with cardiovascular risks. A Survey Monkey was circulated after each event to capture the views of participants and to ensure that it was seen as a useful event.

Results: In total, around 60 members of the pharmacy team (pharmacists, technicians, and ATOs) attended the events, the majority being pharmacists. In total, 28 responses were received.

- The event was rated as **4.3 out of 5** for usefulness to practice.
- **79%** stating that the case studies were at the right level in terms of balance between mental and physical health.
- **93%** felt it raised their awareness of the interaction between physical and mental health within their practice.
- **100%** stated that they felt the event was a positive step towards integration of services to improve patient care.
- Just under **60%** had changed their practice as a result of the knowledge gained.

Conclusions: Staff involved in the events found them extremely beneficial and the positive outcome is that we believe patient care has

improved as a result. Professional networks have increased and communication between the acute and mental health trust, especially at the interface is also improved.

Going forward acute trusts in our other geographical localities have seen these events and are in the process of arranging similar ones.

Medicine information leaflets in Asia, Africa, and the United Kingdom: A scoping review of the literature

P. Nualdaisri^{1,2}, S.A. Corlett², J. Krska²

¹Faculty of Pharmaceutical sciences, Prince of Songkla University, Thailand, ²Medway School of Pharmacy, Universities of Kent and Greenwich, UK

Background: Patient information leaflets (PILs) are a tool for enhancing patient safety of medicines. Providing patients with suitable information is vital to encourage their appropriate use and understanding of the likely benefits and risks of medicines.¹ The provision of PILs has been regulated in the United Kingdom since 1977,² and much research has been conducted in this area. A systematic review published in 2007, which summarised research in written medicine information, included no studies in either Asia or Africa.³

Aim: To review all studies on the provision of medicine information for patients in Asia and Africa in comparison to studies in the United Kingdom.

Methods: A literature review was carried out using Medline, CINAHL, Web of Science, and Scopus to identify original articles focusing on any aspect of medicine information from 2004 to 2017 in Asia, Africa, and the United Kingdom. Empirical research and abstracts written in English were included. Duplications were deleted. The articles were sorted by country of origin and separated into three groups dependent upon their main focus: (1) content and/or design, (2) patients' attitudes towards PILs or the impact of PILs on knowledge or behaviour, and (3) sources of medicine information used by patients.

Results: A total of 843 articles were identified. Six hundred ninety-two of these were excluded because they were either not conducted in the target countries or not specific to medicine information. There were 23, 79, and 49 from Africa, Asia, and the United Kingdom, respectively. In Africa, 11 studies focused on the impact of PILs on patients' behaviour and six involved user testing. In contrast, a large proportion of studies in Asia (40) assessed only the content of PILs, 19 were patient surveys relating to sources of medicine information and relatively few (9) assessed the impact of PILs. Almost all studies in the United Kingdom either assessed impact of PILs on patients' understanding of information or involved user-testing.

Group (1) studies on PILs mainly evaluated the content, by collecting a wide variety of PILs and comparing them with either domestic or international regulations, literature, or best evidence. Some studies also evaluated readability utilising validated criteria, eg, Flesch-Kincaid, SMOG. In other studies, PILs were redesigned with new content such as pictograms, headline sections or benefit information, often followed by user testing.

Group (2) studies involving patients were conducted to test the impact of PILs in term of change in knowledge as well as assessing patients' attitudes, acceptability, perceptions, and behaviour. These studies used several methodologies including randomised controlled study, before-after method, and cross-sectional surveys.

With regard to sources of medicine information, most group (3) studies used quantitative cross-sectional surveys to identify different sources used by patients to obtain medicine-related information, with PILs being one of these. A few articles were qualitative studies.

Conclusions: Studies on PILs undertaken in Africa and Asia are limited in term of volume in comparison to research in the United Kingdom and differ in their focus and methods used. The next stage is to assess the quality of studies identified.

REFERENCES

1. Horne R, Hankins M, Jenkins R. The satisfaction with information about medicines scale (SIMS): a new measurement tool for audit and research. *Qual Health Care*. 2001; 10:135–40.
2. Working Group on Patient Information. Always Read the Leaflet Getting the best information with every medicine. Available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/391090/Always_Read_the_Leaflet_getting_the_best_information_with_every_medicine.pdf (accessed September 03, 2018).
3. Raynor DK, Blenkinsopp A, Knapp P, Grime J, Nicolson DJ, Pollock K, et al. A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines. *Health Technol Assess* 2007;11(5).

Developing a novel information-support app for cancer clinical trials; findings from a patient and public involvement and engagement focus group

A.I. Chatzixenitidis¹, A. Gifford¹, B. Murray², S.R. Chapman¹

¹School of Pharmacy, Keele University, Newcastle-under-Lyme, England,

²Royal Stoke University Hospital & Keele University Hospitals of North Midlands NHS Trust, Stoke-on-Trent, England

Background: Mobile health (mHealth) can potentially provide patients with readily available platforms to support their needs. As such platforms are highly user-orientated, developers need to consult with potential users during the early development stage of these interventions to ensure that they adequately reflect the needs of the end population (Darlow and Wen, 2016). This study presents the Patient and Public Involvement and Engagement (PPIE) phase of the development process of an app delivering information using avatars (virtual clinicians) for patients offered entry to a clinical trial for breast cancer.

Aims and objectives: To collect patients' perspectives in order to establish the content and technical features of an app for consenting to a breast cancer trial.

Methods: Four women with previous experience in clinical trials for breast cancer were invited to attend a focus group. A semi-structured topic guide was used to facilitate the discussion, and framework analysis was deployed to analyse the findings.

Results: Four main thematic categories were identified (experiences from trials and perspectives on medical research; perceived information needs; perspectives about using avatars and apps for information and decision support; and recommendations about the app). Participants held favourable views about taking part in clinical research and reflected positively upon their experiences with trials. The overall feedback regarding the use of avatars was positive, and the prospect of providing such an intervention to fellow patients was received well. The perceived information needs were associated with general information about trials and specific information about the trial they were invited to, with particular emphasis upon safety and risk management. Finally, the recommendations regarding the design of the app included instructions about the avatars (customisation potential, professional appearance, resembling characteristics of someone known to them), ideas about the content (organisation of the content, framing of information, and level of detail) and suggestions about the functions of the app (glossary, section for explaining the trial to children, and timeline of the trial).

Conclusions: The most significant findings were associated with the content of the app and the appearance of the avatars. Participants pointed out that the content should contain more than plain information such as statistics or lists of side effects and be as explanatory as possible in order to aid their understanding. With regards to the appearance of the avatars, participants suggested that different avatars should be used for delivering different types of information (e.g. oncologists for the scientific information and nurses for emotional support and sexual information) and that a separate avatar should be formulated for explaining trials to their children, as another child or a cartoon figure can potentially inspire more comfort than healthcare professionals to them.

REFERENCES

1. Darlow S and Wen K, "Development testing of mobile health interventions for cancer patient self-management: A review", *Health Informatics J*, 2016; 22(3): 633–650.

Apixaban dosing for inpatients requires pharmacist or specialist nurse input

M. Wilcock¹, L. Kelly¹, E. Dryden¹, A. McSorley²

¹Pharmacy Department, Royal Cornwall Hospitals NHS Trust, Truro,

²Lead Anticoagulant Nurse, Royal Cornwall Hospitals NHS Trust, Truro

Background: Apixaban requires complex dose adjustment for prevention of thromboembolism in nonvalvular atrial fibrillation (NVAf). The dose is 5mg twice daily, reduced to 2.5mg twice daily in patients with severe renal impairment (creatinine clearance 15–29 mL/min), and also in those with ≥ 2 of the following criteria: age ≥ 80 years, body weight ≤ 60 kg, or serum creatinine (SCr) ≥ 133 micromole/L. The rate of real world reduced dose prescribing is noted to be considerably higher than the 4.7% seen in a pivotal trial¹.

Aim: The aim was to measure compliance with apixaban dosing recommendations for NVAf in an inpatient setting in a 750 bedded teaching district general hospital.

Methods: Data were extracted from the hospital electronic prescribing system for patients prescribed apixaban for any indication for 6 months to March 2018. Records for those with suspected inappropriate dosing due to age, weight, or SCr were viewed for clinical details as necessary, including indication, e.g. for NVAf or other thromboembolic disease. Data were analysed using Microsoft Excel. This study did not require ethics approval.

Results: There were 447 patients prescribed apixaban—37.1% (166/447) on 2.5mg dose and 62.9% (281/447) on 5mg dose, noting that patients were treated for various indications, not exclusively NVAf. Mean age of all patients was 77 years (84 years for those on 2.5mg dose and 73 on 5mg dose). Only 96 patients had a weight documented in the electronic prescribing system.

We identified 22 patients receiving 2.5mg dose for NVAf who did not meet the criteria—Thirteen patients had none of the three criteria (age, weight, SCr), and a further nine patients with a weight > 60 kg but who had only one criterion (either age or SCr) for the low dose. This is a minimum 13.3% of the total 166 low dose patients (some of whom would have had this dose for indications other than NVAf).

There were also two patients on 5mg dose for NVAf who during their admission had two of the three criteria (both aged over 80 years with SCr ≥ 133 micromole/L) indicating they should be on 2.5mg.

Conclusion: There was apparent under dosing of apixaban in 22 patients with NVAf. This is a minimum of 13.3% (22/166) of our patient cohort on low dose for any indication.

Limitations of our study include being located in just one hospital, no knowledge of how many patients were actually treated for NVAf, a documented weight was missing for many patients, and it was not always clear if the hospital commenced treatment or the patient was admitted on apixaban.

Others have reported on high proportion of patients in whom inappropriately low doses of apixaban are used², generally because the clinician perceives the patient to be at high bleeding risk.³

We intend to have education sessions to raise awareness of dosing advice for clinical staff and encourage pharmacists to check more closely apixaban dosing.

REFERENCES

1. Granger CB, Alexander JH, McMurray JJ, Lopes RD, *et al.*, "Apixaban versus warfarin in patients with atrial fibrillation", *N Engl J Med*, 2011; 365(11):981–992.
2. Pirrie J, Starrs J, Sorensen P., "Audit of apixaban prescribing for atrial fibrillation", *Int J Pharm Pract*, 2016; 24 (Suppl 3):37.
3. Gibson CM, Smith CB, Davis S, Scalese MJ., "Assessment of apixaban prescribing patterns for nonvalvular atrial fibrillation in hospitalized patients", *Ann Pharmacother*, 2018; 52(1):54–59.

A virtual patient educational programme to teach counselling to clinical pharmacists—development and proof of concept

C.L. Richardson, S. White, S. Chapman

School of Pharmacy, Keele University, Staffordshire, UK

Background: Counselling can positively impact patient care, empower patients to adopt self-management of medicines and increase patient satisfaction[1]. It is important that pharmacists providing drug-specific counselling are suitably trained with knowledge and skills. A virtual patient (VP) tool on the topic of non-vitamin K oral anticoagulants (NOACs) to treat atrial fibrillation has been developed to teach pharmacists NOAC counselling. The VP may be used for continuing professional development.

Aim: To develop and show proof of concept of the VP educational tool.

Methods: A three-way cyclic development approach was adopted whereby the development team, a steering group, and Bayer AG as the client informed VP design, content and aesthetic. The steering group of pharmacists provided data for VP development, exploring the VP concept. Their brief was to advise on the case to ensure it was realistic, clinically accurate, and appropriate for use. This included formal and informal evaluation; ethical approval was not required. Feedback areas consisted of a number of VP elements: technological feedback, text (clinical content and style), spoken text, pictures/visual effects, and case feedback. During development, feedback was deliberated by the involved parties to inform design.

Results: Positive feedback on the VP concerned the technology and the high-standard of animations. Negative elements concerned international VP use and differences in practice. Feedback suggested that the reviewers liked the VP concept but that delivery on different devices could be improved. Some data supported that the smartphone version was more usable than the computer version but one reviewer was opposed to using a mobile phone for learning. The VP was designed to be available on various devices, in keeping with the intention for the VP to be as accessible as possible.

The VP was reported to be "valuable" and realistic with high-quality animations. The VP's potential for training newly qualified pharmacists was highlighted. Suggested improvements included the option to print or save a PDF of personalised feedback. This has now been added to allow for written feedback to confirm learning. Written feedback can also be used to document continuing professional development.

Increased user feedback was suggested by the reviewers with proposals of incorporating a pass/fail mark. The lack of a pass/fail mark was an intentional design feature as there is not necessarily a "correct answer" to the VP. It was hoped that this would empower participants to reattempt the case and explore alternative pathways, as well as to promote reflection, in keeping with pedagogy rationales of problem-based learning and theories of reflective learning through practice[2].

Conclusion: The VP met the needs of the client and their application. Development was effective, in that a VP was created that is clinically accurate, realistic, and useful, from the steering group's point of view, demonstrating proof of the VP concept. This will inform future VP development and encourage VP use in the pharmacy profession; a large-scale VP evaluation is underway.

REFERENCES

1. Pereira D, Cavaco A. Exploring computer simulation to assess counselling skills amongst pharmacy undergraduates. *Indian J Pharm Educ Res*. 2014;48:17–26. doi:10.5530/ijper.48.1.4

2. Bearman M, Cesnik B, Liddell M. Random comparison of 'virtual patient' models in the context of teaching clinical communication skills. *Med Educ* 2001;35:824–32. doi:10.1046/j.1365-2923.2001.00999.x

Penicillin allergy status in primary and secondary care

S. Barrett, W. Baqir, D. Campbell, S. Ellis, N. Premchand

Background: Among all allergic reactions to antibiotics, penicillin is one of the most commonly reported with 5%-10% of patients having a documented allergy to penicillin.^[1] However, incidence of penicillin-related anaphylaxis has been reported to be in the region of 0.01% to 0.04%.^[2] A debate is growing on the nature of reported allergy status, highlighting the association between reported allergy status and a history of clinically significant IgE-mediated reactions.^[1] Whilst work has demonstrated that clinicians considered history and severity of allergy when selecting antibiotics in patients with an allergy to penicillin recorded,^[3] some authors suggest that half of allergies reported by patients may not have an immunological origin.^[4] This raises concern in that patients with a documented penicillin allergy may not receive first-line penicillin-containing treatments and instead may be treated with second-line agents. Second-line agents may be less cost-effective, and the unnecessary overuse of these agents may represent opportunities to improve patient treatment outcomes. This study aimed to explore reported levels of penicillin allergy across primary and secondary care.

Methods: Over a period of 1 week, all patients admitted to one hospital were audited for penicillin allergy status. A second study was carried out to identify the number of patients with reported penicillin allergy in electronic primary care records.

Results: An audit of hospital admissions (across Northumbria Healthcare NHS Foundation Trust) over 4 weeks found 12% ($n = 326$) of 2720 of patients had a documented penicillin allergy whilst within primary care records, penicillin allergy status was recorded in 6.2% ($n = 77$) of 1237 patients.

Conclusion: Across both settings, almost one in 10 patients are recorded to be allergic to penicillin, thus being at risk of not receiving optimal treatment if they needed it. Urgent work is needed to assess these patients to identify those truly allergic. By doing so, we reduce risk of harm, reduce healthcare costs, and protect limited antibiotic agents against resistance.

REFERENCES

1. Macy E, Contreras R. Health care use and serious infection prevalence associated with penicillin "allergy" in hospitalized patients: a cohort study. *J Allergy Clin Immunol*. 2014; 133:790.
2. Allergic reactions to long-term benzathine penicillin prophylaxis for rheumatic fever. International rheumatic fever study group. *Lancet*. 1991; 337:1308.
3. Solensky R, Earl HS, Gruchalla RS. Clinical approach to penicillin-allergic patients: a survey. *Ann Allergy Asthma Immunol* 2000;84(3):329.
4. Kerr, J. R.: Penicillin allergy: a study of incidence as reported by patients. *Brit. J. Clin. Pract.* 1994, 48, 5–7